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| 10/532,285 | 11/22/2005 | James P. Beck | 02-1107-A1 | 8774 |

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| EXAMINER | |
|---|---|
| JEAN-LOUIS, SAMIRA JM | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/532,285 | BECK, JAMES P. | |
| | Examiner | Art Unit | |
| | SAMIRA JEAN-LOUIS | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *5-17 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-17 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

**The Examiner for this current application at the USPTO has changed. Examiner Samira Jean-Louis can be reached at 571-270-3503.**

***Response to Amendment***

**This Office Action is in response to the amendment submitted on 02/21/2008.** Claims 5-17 and 30-32 are pending in the applications, with claims 1-4 and 18-29 having being cancelled. Accordingly, claims 5-17 and 30-32 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Examiner further acknowledges amendment of claims 5-17 and 30-32 and deletion of the word "preventing". Consequently the enablement rejection under 35 U.S. C. 112, first paragraph has been withdrawn.

Examiner further acknowledges amendment of claims 5-17 and 30-32 and recitation of the specific disease, Alzheimer's disease. Consequently the enablement rejection under 35 U.S. C. 112, first paragraph has been withdrawn.

Applicant's arguments against the 35 USC 112 1rst paragraph rejection of claims 1-17 and 30 has been fully considered and is found persuasive. Given that applicant did describe the invention in detail and the manner and process of making and using the invention, the lack of written description rejection of claims 1-17 and 30 is withdrawn.

Applicant's argument that Bennett in view of Esiri does not render obvious applicant's invention has been fully considered and is found persuasive. Indeed, Bennett teaches the compounds of formula I of the instant application and elected species Compound A in the treatment of AIDS and for inhibiting HIV-1 protease. Esiri, on the other hand, teaches that AIDS patients tend to have an increase of beta amyloid plaques which are characteristic factors in Alzheimer disease. However, Esiri et al. does teach that anti HIV treatment did not result in reducing plaque formation which essentially does not render obvious other HIV or AIDS treatment for this subset of AIDS patients with the aforementioned compounds. As a result, the 103 (a) rejection of claims 1-2 and 5-17 are withdrawn.

However, in view of applicant's amendment to the claims, the following 112, 1rst paragraph Enablement Non-Final rejection is being made.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-17 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for any of the disclosed compounds in the specification (see pages 17-19 and 22) including the elected compound, Compound A. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of treating a subject who has Alzheimer's disease and who is in need of such treatment which includes administration of a therapeutically effective amount of a compound of formula I, an epimer or racemate thereof. The instant specification fails to provide information that would allow the skilled artisan to practice the treatment of Alzheimer's disease with the aforementioned compounds given that the prior art teaches these compounds as effective against HIV-1 enzyme or AIDS treatment.

[In re Sichert, 196 USPQ 209 (CCPA 1977)]

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC

1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to a method of treating a subject who has Alzheimer's disease and who is in need of such treatment which includes administration of a therapeutically effective amount of a compound of formula I, an epimer or racemate thereof. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not

of the art, the examiner cites Bennet (previously submitted) who describes the compounds of the instant invention as useful for the treatment of AIDS or HIV infection and useful in inhibiting HIV-1 protease **and not** beta-amyloid converting enzyme.

2. The breadth of the claims

The claims are thus very broad insofar as they recite the "treatment of Alzheimer disease" with the same aforementioned compounds of Bennet. While applicant delineated various assays and model systems that could be potentially be used to determine the inhibitory activities of the aforementioned compounds, applicant failed to provide any evidence that the aforementioned compounds actually do inhibit beta-amyloid converting enzyme or if the compounds actually do treat Alzheimer disease.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance or working examples of the use of these compounds in the treatment of Alzheimer's disease or in the inhibition of beta amyloid converting enzyme. While applicant provided specific guidance concerning useful therapeutic protocols and animal model system that can be used for determining the efficacy of these compounds in treating Alzheimer's disease or inhibiting beta amyloid converting enzyme, applicant does not reasonably enable one

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"experimentation".

skill in the art to practice the claimed invention without undue experimentation. In fact, applicant provided no working examples.

While prophetic examples may describe an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved, one skilled in the art should be able to practice it without an undue amount of experimentation. *In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).***See M.P.E.P. 2161.**

Moreover, the instant disclosure provides no evidence to suggest that this unique activity can be extrapolated to Alzheimer's disease, especially given that the prior art teaches these compounds for the treatment of AIDS and HIV infection. Thus, the instant claimed invention does not meet the "how to use" prong of 35 USC 112, first paragraph with regard thereto.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used for the treatment of Alzheimer's disease or for inhibiting beta amyloid converting enzyme as inferred by the claims and contemplated by the specification given that the prior art teaches these compounds as useful in the treatment of HIV infection and AIDS and given that these two diseases are contrastingly different. Accordingly, the instant claims do not comply with the

enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

In conclusion, applicant is not enabled for a method of treating a subject who has Alzheimer's disease and who is in need of such treatment or a method for modulating beta amyloid converting enzyme which includes administration of a therapeutically effective amount of a compound of formula I, an epimer or racemate thereof given that the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

05/07/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617